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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,281	06/06/2001	Anthony Viole	FORFLOW.008A	8796

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[Redacted] EXAMINER

YU, JEANNE C

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	09/876,281	Applicant(s) VIOLE ET AL. <i>Ch</i>
Examiner	Art Unit	
Jeanne Yu	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 October 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-49 is/are pending in the application.

4a) Of the above claim(s) 3,13-26,31-37,42,46 and 49 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,2,5-12,27-30,38-45,47 and 48 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2,6,8</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Response to Preliminary Amendment

Applicant's new claims, 44-49, in Paper No. 10 are acknowledged. Of these claims, claim 44 is independent.

Election/Restrictions

Claims 35-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

Applicant's election of Figure 3 in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 3, 13-26, 31-34, and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Claims 42 and 49 have also been withdrawn from further consideration because the disclosure does not support a third lumen or Y-connector in the elected species of Figure 3. Election was made **without** traverse in Paper No. 10.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 4 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is insufficient antecedent basis for the following limitations:

Claim 4 recites the limitation "the at least one aperture" in line 24.

Claim 41 recites the limitation "the active perfusion means" in line 8.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Aigner USPN 4,540,402.

Re claim 1, Aigner discloses a multilumen catheter 1 (Fig 1) comprising a proximal end along line B, a first distal end marked by 6, a second distal end marked by 5, wherein the first distal end extends distally further from the proximal end than the second distal end; a first lumen 6 extending between the first distal end and the proximal end; and a second lumen 5 extending between the second distal end and the proximal end.

Re claim 2, Aigner discloses at least one aperture 4 in one of said lumens positioned near the proximal end. The aperture or lateral opening(s) 4, which insure circulation of the blood (c 5, l 32-36), is read as being capable of maintaining or enhancing perfusion of blood to the patient's vasculature downstream of where the aperture resides in the vasculature because when the catheter is inserted into the patient for treatment, blood flow downstream will flow through the aperture 4.

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3. Claims 1, 5, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Marhurkar USPN 4,134,402.

Re claim 1, Marhurkar discloses a multilumen catheter 1 (Fig 1) having a proximal end along line V, a first distal end 5, and a second distal end 4, wherein the first distal end 5 extends distally further from the proximal end than the second distal end 4 (c 2, l 24-26); a first lumen 3 extending between said first distal end 5 and said proximal end; and a second lumen 2 extending between said second distal end 4 and said proximal end. See Figure 1.

Re claims 5 and 6, Marhurkar discloses a multilumen catheter 1, wherein the first distal end 5 is tapered, and the second distal end 4 is tapered. See Figure 1.

Re claim 8, Marhurkar discloses a multilumen catheter 1, wherein said distal end 4 of the second lumen 2 comprises at least one distal aperture 32 (Fig 1).

4. Claims 1, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Palestrant USPN 5,618,267.

Re claim 1, Palestrant discloses a catheter 20 (Fig 1) having a proximal end 24, or a trailing end, and a distal end 22, or a leading end (c 6, l 27-29). Palestrant further discloses first strip 32 and second strip 38 forming a first lumen (c 3, l 19-21). See Figure 3. The first strip 32 and second strip 38 extending the length of the catheter (c 6, l 41-47) is read as a first lumen extending between a first distal end and the proximal end. '267 further discloses a second lumen 86 (Fig 11) having the same length as the first lumen (c 9, l 66-67 and c 10, l 1-3), which is read as a second lumen 86 extending between a second distal end, or exit port, and the proximal end. Lastly, Palestrant

discloses a shorter second lumen 86 such that the exit port is longitudinally displaced from the exit port of the first lumen (c 10, l 3-7), which is read as the first distal end extending distally further from the proximal end than the second distal end.

Re claims 11 and 12, Palestrant discloses a multilumen catheter (Fig 11) comprising a radiopaque marker, wherein the radiopaque marker may be used to position the catheter when the catheter is applied to a patient (c 3, l 42-45). The radiopaque marker, or radiopaque wire 68 (c 3, l 49), is read as an indicator near the proximal end because it extends along the seam of the catheter (c 8, l 24-26), i.e. extending from the proximal end.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolling et al. USPN 6,390,969 B1 in view of Marhurkar USPN 4,134,402.

Bolling discloses the claimed invention comprising:

a multilumen catheter 510 (Fig 8) having a proximal end and a distal end; a first lumen 514 extending between the distal end and the proximal end; a second lumen 516 extending between the distal end and the proximal end (claim 1);
an outflow conduit (indicated by arrow flowing towards the pump in Fig 8) fluidly engaged to one lumen 514 (Fig 8) and an inflow conduit (indicated by arrow

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flowing away from the pump in Fig 8) fluidly engaged to the other lumen 516 (Fig 8) (c 16, l 65-67), wherein the inflow and outflow conduits are fluidly coupled to a pump so that when connected to a patient, the pump circulates blood into the distal end of lumen 514 and out the distal end of lumen 516 (c 17, l 1-15) (claim 4).

Bolling does not disclose expressly:

a catheter having a first and second distal ends, wherein the first distal end extends distally further from the proximal end than the second distal end (claim 1);
one of the distal ends comprising at least one distal aperture (claim 7), wherein a pump circulates blood through at least one aperture (claim 4).

Marhurkar discloses a multilumen catheter 1 (Fig 1) having a first distal end 5, and a second distal end 4, wherein the first distal end 5 extends distally further from the proximal end than the second distal end 4 (c 2, l 24-26), and wherein the distal end 4 comprises at least one distal aperture 32 (Fig 1). Bolling and Marhurkar are analogous art because they are from a similar problem solving area, i.e. withdrawing and returning blood by means of a double lumen catheter. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the double lumen catheter of Bolling with the double lumen catheter of Marhurkar. The motivation for doing so would have been to insure that blood returned through the blood return lumen will not be carried into the blood intake lumen (Marhurkar, c 1, l 61-67) and to aid blood flow (Marhurkar, c 2, l 45-48). Therefore, it would have been obvious to combine Bolling and Marhurkar to obtain the invention as specified in claims 4 and 7.

6. Claims 27-30, 38- 41, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolling et al. USPN 6,390,969 B1 in view of Aigner USPN 4,540,402.

Bolling discloses an extracardiac pumping system comprising:

a pump configured to pump blood through the patient at subcardiac flow rates, or substantially below that of the patient's heart (c 6, l 11-24 and c 10, l 26-27) (claim 27);

an inflow conduit (indicated by arrow flowing towards the pump in Fig 8) fluidly coupled to the pump to direct blood to the pump 32 to direct blood to the pump from a first blood vessel and an outflow conduit (indicated by arrow flowing away from the pump in Fig 8) fluidly coupled to the pump to direct blood from the pump to a second blood vessel (c 7, l 18-24) (claim 27);

a multilumen catheter 510 (Fig 8) having a proximal end and a distal end; a first lumen 514 extending between the distal end and the proximal end; a second lumen 516 extending between the distal end and the proximal end (claims 27, 38); and

the outflow conduit in fluid communication with first lumen 514 (see Fig 8) and the inflow conduit in fluid communication with second lumen 516 (see Fig 8) (claim 29), or in a reverse-direction (c 11, l 36-42) such that the first lumen 514 is in fluid communication with the inflow conduit and the second lumen 516 is in fluid communication with the outflow conduit (claim 30).

Aigner discloses a multilumen catheter 1 (Fig 1) comprising:

a proximal end along line B, a first distal end marked by 6, a second distal end marked by 5, wherein the first distal end extends distally further from the proximal end than the second distal end (claims 27, 38); and

at least one aperture 4 in one of said lumens positioned near the proximal end.

The aperture or lateral opening(s) 4, which insure circulation of the blood (c 5, l 32-36), is read as a means for maintaining or enhancing perfusion of blood to the patient's vasculature downstream of where the aperture resides in the vasculature by active perfusion means because when the catheter is inserted into the patient for treatment, blood flow downstream will flow through the aperture 4 (claims 28, 38, 39, 41, 43). The lumen 6 is read as a means for maintaining or enhancing perfusion by passive perfusion means (claim 40).

Bolling and Aigner are analogous art because they are from a similar problem solving area, i.e. the removal and return of blood. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the multilumen catheter of Bolling with the multilumen catheter of Aigner. The motivation for doing so would have been to provide an L-shaped catheter to a blood vessel, having a hole, for directing some blood flow downstream of the connector during withdrawal of blood from the vessel such that ischemic damage downstream will be avoided (Bolling, c 13, l 52-58). Therefore, it would have been obvious to combine Bolling with Aigner to obtain the invention as specified in claims 27-30, 38- 41 and 43.

7. Claims 1, 9, 10, 44, 45, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolling et al. USPN 6,390,969 B1 in view of Aigner USPN 4,540,402 as applied to claims 27-30, 38- 41 and 43 above, and further in view of Afzal USPN 6,083,198.

As discussed in section 7 of this action, Bolling et al. as modified by Aigner discloses the claimed invention, including a tip located at the first distal end of the catheter 1 (Aigner, see Fig 1), but does not disclose expressly:

a means for connecting a first conduit to the first lumen and for connecting a second conduit to the second lumen (claim 44)

means for maintaining or enhancing perfusion comprises an aperture (claim 45).

the tip configured as a J-tip comprising a bend (claims 9, 47), wherein the J-tip further comprises an aperture positioned at the distal-most portion of the bend, or proximal the distal end (claims 10, 48).

Afzal discloses a catheter 10 (Fig 1) comprising:

means for connecting a first conduit to the first lumen and for connecting a second conduit to as second lumen, i.e. a Y-shaped connector (c 4, l 62-63) (claim 44);

means for maintaining or enhancing perfusion comprising an aperture 14 (c 4, l 57-59, Fig 1) (claim 45);

a distal end configured as a J-shape comprising a bend (Fig 1) (claims 9, 47), wherein the J-shape further comprises apertures 14 (Fig 1) positioned at the distal-most portion of the bend (claim 10), or proximal the distal end (claim 48).

Aigner and Afzal are analogous art because they are from a similar problem solving area, perfusion catheters. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the first distal end of Aigner with the J-shape bend of Afzal. The motivation for doing so would have been to couple a multilumen catheter to a single pump (Afzal c 4, l 63), to pump or deliver oxygenated

blood via the apertures 14 (Afzal, c 4, l 36-38) and to enable a catheter to be positioned within the aortic root AR (Afzal, Fig 1). Therefore, it would have been obvious to combine Bolling et al. as modified by Aigner, and further modified by Afzal, to obtain the invention as specified in claims 9, 10, 44, 45, 47 and 48.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patents are cited to further show the state of the art with respect perfusion catheters:

USPN 6,044,845 to Lewis

USPN 6,059,760 to Sandmore et al.

USPN 5,522,800 to Crocker

USPN 4,944,745 to Sogard et al.

USPN 5,087,247 to Horn et al.

USPN 6,371,935 to Macoviak et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeanne Yu whose telephone number is 703-305-7569. The examiner can normally be reached on Monday-Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



JCY

December 30, 2002



MARK BOCKELMAN
PRIMARY EXAMINER